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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

(Attorney Docket No. 01-1096)

In re Application of:

Fritz et al.

Serial No. 09/780,206

Filed: February 9, 2001

For: System for Simple Nucleic
Acid Analysis

Examiner S. Chunduru

Group Art Unit: 1637

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Dear Sir:

In regard to the above identified application,

1. We are transmitting herewith the attached:
- a) Response to Office Action mailed June 26, 2003
 - b) Return receipt postcard.
2. With respect to fees:
- a) No Fee is Required.
 - b) Please charge any underpayment or credit any overpayment our Deposit Account, No. 13-2490.

Respectfully submitted,

Patrick G. Gattari

Registration No. 39,682

McDonnell Boehnen
Hulbert & Berghoff
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Chicago, IL 60606

CERTIFICATE OF MAILING (37 C.F.R. 1.8a)

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RESPONSE TO OFFICE ACTION MAILED JUNE 26, 2003

In response to the Office Action mailed June 26, 2003, please consider the following Remarks. No claim is amended.

Claims 36-41 and 68 are pending in the application. Claims 42-67 were previously withdrawn from consideration pursuant to a Restriction Requirement.

In the Office Action, the Examiner has maintained the rejections under 35 U.S.C. § 102 over Furcht *et al.* In the rejection of claims 36 - 41, the Examiner points to the Remarks from Applicants' previous Response stating that the claimed device is an integrated device for detecting nucleic acids such that the binding and amplification of nucleic acids are carried out in the same space. The Examiner asserts that this limitation from the specification cannot be read into the claims. Specifically, the Examiner states that Applicants' previous statement that "binding as well as amplification are carried out in the same space" is not in independent claim 36.

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Applicants respectfully direct Examiner's attention to part (b) of claim 36 where the claim recites "an application space for amplifying nucleic acids comprising at least part of the binding space" Furcht *et al.* does not teach this limitation in an integrated device such as the present invention. As applicants have previously described, Furcht *et al.* teach several components that are combined only in the course of the detection procedure, *i.e.*, the FTA matrix collection device (Fig. 1, No. 11) is contacted with the sample before being inserted into a sample access port on the gene test card (Fig. 1, No. 14, col. 9, lines 24-43). This is completely different than the presently claimed *integrated* device that does not require a manipulation of the components such that sample is added to one component before the component is inserted into the device. Moreover, Furcht *et al.* does not teach the separation of impurities in an integrated format as in claim 1. Instead, Furcht *et al.* teach that "processing of the specimen involves an external reagent washing of the FTA treated sample collection pad ... to remove[] all PCR-inhibitory compounds" (col. 9, lines 24-32) (emphasis added). This is another example that Furcht *et al.* does not teach the presently claimed invention.

Accordingly, Furcht *et al.* does not teach each and every element of the *integrated* device of independent claim 36. In addition, dependent claims 37 – 41 contain all of the limitations of independent claim 36. Accordingly, Applicants respectfully request that the rejection pursuant to 35 U.S.C. § 102 to claim 36 – 41 be withdrawn.

With regard to claim 68, the Examiner has maintained the rejection pursuant to 35 U.S.C. § 102 based upon Furcht *et al.* According to the Examiner, the two opposed, spaced-apart microchip heaters taught in Furcht *et al.* are equivalent to the limitation of claim 68 that the "capillary reaction vessel [is] surrounded by heatable metal layer wherein the layer is coated on the capillary reaction vessel." The Examiner states that since the claim is an open ended "comprising" claim, additional elements can be included to meet the limitations as taught by Furcht *et al.* While Applicants agree that claim 68 is open ended, Applicants disagree with Examiner's anticipation analysis. The test for anticipation is not whether additional limitations can be added to the present claim to meet all of the limitations of Furcht *et al.* Instead, in order for Furcht *et al.* to anticipate the presently claimed invention, Furcht *et al.* must teach each and every element of

independent claim 68. Furcht *et al.* does not teach each and every element because Furcht *et al.* does not teach that a metal heating element surrounds the reaction vessel. Examiner states that the present claim is anticipated because the claim does not state that the heatable metal layer is a continuous layer around the reaction vessel. However, "surround," in its ordinary sense, means "1. To extend on all side of simultaneously; encircle; 2. To enclose or confine an all sides." American Heritage Dictionary, 3rd Ed., Dell Publishing, New York, NY (1994). Clearly, the limitation "surround" is not met by the two opposed spaced-apart microchip heaters taught in Furcht *et al.*

Furthermore, Furcht *et al.* does not disclose a heatable metal layer where the layer is coated on the capillary reaction vessel. The Examiner refers to column 10, lines 28-33 of Furcht *et al.* as teaching a "epoxy-like material" that is deposited on a silicon wafer to form the reservoirs and interconnecting capillary of the device. However, this disclosure does not teach the heatable metal layer of present claim 68 since the material in Furcht *et al.* is an epoxy material, not metal as recited in claim 68. Moreover, nothing in Furcht *et al.* teaches that the layer is coated on the vessel.

Accordingly, Furcht *et al.* fails to teach each and every element of claim 68 because Furcht *et al.* does not teach a metal layer that surrounds the reaction vessel as recited in claim 68. Therefore, Applicants respectfully request that the rejection of claim 68 under 35 U.S.C. § 102 be withdrawn.

Claims 36-41 and 68 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Burns *et al.* (U.S. Patent No. 6,379,929). Applicants respectfully disagree with this rejection because Burns *et al.* does not teach each and every element of the independent claims 36 and 68.

Regarding claim 36, Burns *et al.* does not teach a binding space for purifying nucleic acids by immobilizing the nucleic acids and separating impurities. In addition, Burns *et al.* does not teach that the binding space comprises at least part of the amplification space. The Examiner cites to Burns *et al.* at column 3, lines 66-67 and column 4, lines 1-4 and lines 22-39 as teaching a binding space (substrate) for purifying and immobilizing the nucleic acids and separating impurities. However, nothing in this

disclosure teaches a binding space for immobilizing and purifying nucleic acids. In addition, nothing in this disclosure or anywhere else in Burns *et al.* teach the separation of impurities. Apparently, the sample is processed before it is inserted into the device taught by Burns *et al.*

Moreover, the Examiner states that Burns *et al.* teaches an amplification space (reaction chamber) comprising at least part of the binding space (substrate) for amplifying nucleic acids and refers to columns 5, lines 58-64, column 4, lines 1-4 and 49-67 and column 5, lines 1-3. However, none of these citations to Burns *et al.* teach a binding space for purifying and immobilizing nucleic acids that is also part of the reaction chamber. Column 4, lines 1-4 of Burns *et al.* teach a transport channel operably connected to a reaction chamber. This does not teach that the channel (to the extent that the examiner considers this a binding space) is part of the reaction chamber.

As explained above, Burns *et al.* is missing several of the elements of independent claim 36. Thus, Burns does not anticipate claim 36 or dependent claims 37 – 41 that contain all of the limitations of claim 36. Accordingly, Applicants respectfully request that the rejection pursuant to 35 U.S.C. § 102(e) over Burns *et al.* be withdrawn.

Turning now to claim 68, Burns *et al.* fails to anticipate the present invention because Burns *et al.* fails to teach a capillary reaction vessel surrounded by heatable metal layer that is coated on the vessel. The Examiner points to column 6, lines 7-17 and 46-65 of Burns *et al.* to show this limitation of claim 68. However, Burns *et al.* simply describes that resistors are in contact with or in proximity of the reaction chamber (column 6, lines 8-9). This does not teach a heatable metal layer that is coated on the reaction vessel. Similarly, Burns *et al.* teaches that a series of heating elements maybe arrayed along one or more microdroplet transport channels. Such resistive heaters may be located slightly beneath the channels (column 6, lines 49-52). This disclosure does not teach that the heating element surrounds the reaction chamber as presently claimed in claim 68. Thus, Burns *et al.* does not teach each and every element of independent claim 68. Therefore, Applicants respectfully request that the rejection of claim 68 pursuant to 35 U.S.C. § 102 over Burns *et al.* be withdrawn.

CONCLUSION

With the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. If Examiner is of the opinion that a telephone conference would expedite prosecution of the application, Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted,

McDonnell Boehnen Hulbert & Berghoff

A handwritten signature in dark ink, appearing to read "Patrick G. Gattari", written over a horizontal line.

Patrick G. Gattari

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